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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,428	02/22/2002	Virginia L. Price	3141-A	8280

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EXAMINER	
KETTER, JAMES S	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,428	PRICE ET AL.	
	Examiner	Art Unit	
	James S. Ketter	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/10/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 14-34 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 22 September 2004.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-11 and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gilman et al. in view of La Rossa et al. and further in view of Kushner et al., for reasons of record set forth ion the previous Office Action, mailed 10 August 2005.

At the paragraph bridging pages 5 and 6 of the amendment filed 10 February 2006, Applicants argue that one of skill in the art would not have used serum free medium as the intention in Gilman et al. was to use the cells therein produced for implantation, and Applicants argue that cells from serum-free conditions would be from a more different environment upon transplantation than those disclosed in Gilman et al. As such, it is argued, one of skill in the art would not have been motivated to adapt the cells to serum-free growth, and that Gilman et al. therefore teaches away from the claimed invention. However, it is not apparent that Applicants' assertion that one of skill would have viewed the serum-free environment as problematic or detrimental to practicing the invention resulting from the combination of cited teachings. Kushner et al. teaches that serum-free adaptation and growth was known in the art for producing

recombinant proteins. Gilman et al. teaches, e.g., at column 24, first full paragraph, use of the cells therein disclosed for recombinant production of proteins, clearly alternative to implantation. Thus, there could not have been a teaching away, as implantation would not have been contemplated. In the subsequent paragraph, Applicants argue that CHO cells and the MT promoter used by Kushner et al. are different than those used by Gilman et al and la Rossa et al., and therefore there would not have been any motivation to combine. However, as set forth in the previous Office Action, motivation is provided by Kushner et al. to select CHO cells to practice the method resulting from the combination of Gilman et al. and La Rossa et al.

Applicant's arguments filed 10 February 2006 have been fully considered but they are not persuasive.

Claims 1 and 12 are rejected under U.S.C. 103(a) as being unpatentable over Gilman et al in view of La Rossa et al further in view of Kushner et al. as applied to claims 1, 4-11, and 13 above, and further in view of Levkau et al (applicant reference C8).

Gilman et al., La Rossa et al. and Kushner et al. are described above. These references differ from the invention of claim 12 in that they do not specifically teach the use of caspase-resistant mutant as the p65 transcription factor.

Levkau et al. was described in the previous Office Action, reiterated here: Levkau et al teach a caspase-resistant mutant of p65 (abstract). This p65 mutant is uncleavable and it protects cells from apoptosis more than wild type p65 (page 230-231) This reference also teaches that cleaved p65 is a dominant-negative inhibitor of transcription, suppressing expression from p65-responsive promoters (page 231, second paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the caspase-resistant p65 as the p65 transcription factor used in the methods made obvious from the combined teachings of Gilman et al., La Rossa et al. and Kushner et al., in that Gilman et al and La Rossa make obvious that it is within the ordinary skill in the art to use p65 as the transcription factor in the expression method made obvious from their teachings, and that p65-based transcription factor increased expression is not toxic to cells and Levkau et al. teaches that the caspase-resistant p65 is uncleavable, and that cleaved p65 is a dominant-negative inhibitor of transcription. One would have been motivated to do so for the expected benefit of reducing cleavage of made obvious p65 in the expression system from the combined teachings of the cited references, resulting in less inhibition of expression from p65- responsive promoters, and thus increasing expression from such promoters which include the c-myc promoter.

Although the instant rejection is new, Applicants' arguments with respect to the rejection above would be applicable. Accordingly, for reasons set forth above, it is submitted that said arguments are not persuasive against the instant rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (571) 272-0770. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is

(866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jsk
April 28, 2006

JAMES KETTER
PRIMARY EXAMINER